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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,665

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Hiraku Murayama

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

05/18/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,665	<b>Applicant(s)</b> MURAYAMA ET AL.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12-21, 23, 24, 27, 28, 30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-21, 23, 24, 27, 28, 30 and 32-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 03/03/2009, amended claim(s) 1, 18, 24, 27, and 28 and cancelled claim(s) 25 and 26 is/are acknowledged. The previous rejections of claims 1-3, 12-21, 23-28, 30, and 32-35 is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

2. Initially with respect to Applicant's assertions that claims 19-21, 24-27, 30, and 32-35 were not rejected in the Office Action mailed 12/17/08 and Applicant assumes the claims are allowable (see page 10 filed 03/03/2009), the Examiner disagrees and apologizes for any apparent confusion caused to Applicant.

3. Claims 19-21, 24-27, 30, and 32-35 were clearly listed as rejected on the PTOL-326 Office Action Summary, not listed as objected to or allowed. Moreover the correct listing of the claims was set forth in the Office Action (see paragraph 9 mailed 12/17/08).

4. With respect to the listing of claims rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo in view of Reynolds (see paragraph 4 mailed 12/17/08) claims 19-21, 24-27, 30, and 32-35 were unintentionally omitted.

5. However the 103(a) rejection (see paragraphs 5-8 mailed 12/17/08) clearly set forth the rejection of the scope of claims 19-21, 24-27, 30, and 32-35.

6. As evidenced by Applicant's current amendment of the claims, the scope of at least each of claims 19-21, 24-27, 30, and 32-35 is newly presented and/or the claim(s) cancelled.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al. (US 5,769,796, hereinafter Palermo) in view of Reynolds et al. (US 7,074,197 B2, hereinafter Reynolds).

9. For claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35, Palermo discloses a guidewire (140) (as best seen in Figures 2 and 5A) (column 4 lines 26-32, column 5 lines 45-65, column 6 line 39 – column 7 line 18, and column 8 –line 50 – column 10 line 54), comprising:

- a distally disposed reshapeable and non-superelastic metallic first wire (126) (as best seen in Figure 5A) (the stainless steel as positively recited in column 6 line 39 – column 7 line 18) having a proximal tip (the left tip as best seen in Figure 5A), having a length of 30mm (column 5 lines 19-22), is not a coil (as best seen in Figure 5A), and that is capable of being plastically deformed to a desired shaped being and capable of being maintained in the desired shape upon being bent in the desired shape by a user (the Examiner notes that it is well known in the guidewire art that distally disposed shaping portions may be comprised of stainless steel);

- an intermediately disposed pseudo-elastic alloy second wire (146) (column 4 lines 26-32, column 5 lines 45-65, and the pseudo-elastic Nitinol alloy positively recited in column 8 –line 50 – column 10 line 54) (as best seen in Figure 2) having a smaller elastic modulus than the first wire (column 8 –line 50 – column 10 line 54) and a distal tip (the right tip as best seen in Figure 2),
- wherein the first wire includes a proximal end face (as best seen in Figure 5A) and the second wire includes a distal end face (as best seen in Figure 2),
- wherein said first and second wires are joined at a joined portion (as best seen in Figure 5A) of the end faces of the first and second wires in a nearly perpendicular orientation with respect to the longitudinal axis (as best seen in Figure 5A);
- a proximally disposed third wire (142) (the stainless steel positively recited in column 5 lines 45-65) having a larger elastic modulus than the elastic modulus of the material forming the second wire (column 5 lines 45-65);
- wherein the second and third wire are joined to each other (column 5 lines 45-65) (as best seen in Figure 2) and wherein the guidewire has a taper extending from the proximal end to the distal end (as best seen in Figure 2); and
- a spiral coil (112) (as best seen in Figures 2 and 5A) (column 6 line 39 – column 7 line 18) covering at least the distal end portion of the first wire (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the joined portion between the first and second wires is located distal the proximal end of the spiral coil (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the coil covers the joined portion and is spaced outwardly away from the joined portion (as best seen in

Figure 5A) (column 6 line 39 – column 7 line 18), wherein at least a portion of the spiral coil is located distally beyond a distal end of the joined portion (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the spiral coil possess an axial extent greater than an axial extent of welded portion (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material (128) (as best seen in Figure 5B) (column 6 line 39 – column 7 line 18), and wherein a second fixing material (110) (column 6 line 39 – column 7 line 18) fixes the distal end portion of the spiral coil to the first wire (as best seen in Figure 5A),

- wherein said guidewire ranges in length from 10 to 1,000 mm (column 5 lines 13-17).

10. For claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35, Palermo discloses the claimed guidewire, as set forth and cited above, except for expressly disclosing that

- (a) said first and second wires have a common longitudinal axis, are coaxial, and the proximal tip comprising a proximal end face of the first wire and the distal tip comprising a distal end face of the second wire are nearly perpendicular to the common longitudinal axis and comprise a joined portion;
- (b) the joined portion comprises a welded portion, wherein the welded portion is created by spot or butt-resistance welding; and
- (c) wherein the joined portion between the first and second wires is located proximal the proximal end of the spiral coil.

11. However with respect to (b) and (c), Palermo is expressly concerned with joining and/or attaching the guidewire components (e.g. first, second, and/or third wires) and with regards to said joining and/or attaching explicitly states *inter alia* "attached by soldering or by gluing or by other joining method suitable for the materials involved" (column 5 lines 56-60). Furthermore, the Examiner notes it is well known in the guidewire art to substitute one joining and/or attaching means for another to achieve the predictable result of securely joining and/or attaching adjacent wires.

12. For claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35, Reynolds teaches a guidewire (210) (as best seen in Figures 4 and 9) comprising *inter alia*:

- (a) a first wire (216) and a second wire (214) having a common longitudinal axis (as best seen in Figures 4 and 9) (column 3 lines 7-11, column 3 line 16 – column 4 line 46, column 4 lines 50-51, column 7 line 17 – column 8 line 44, and column 11 line 28 – column 12 line 52), the first wire and the second wire are coaxial as best seen in Figures 4 and 9), and a proximal tip (the left most tip of 216 as best seen in Figures 4 and 9) comprising a proximal end face of the first wire and a distal tip (the right most tip of 214 as best seen in Figures 4 and 9) comprising a distal end face of the second wire are perpendicular to the common longitudinal axis (as best seen in Figure 4) and comprise a joined portion (212) comprising a fused layer (as best seen in Figures 4 and 9) (column 3 lines 7-11, column 3 line 16 – column 4 line 46, column 4 lines 50-51, column 7 line 17 – column 8 line 44, and column 11 line 28 – column 12 line 52);

- (b) the joined portion comprises a welded portion (212) (as best seen in Figures 4 and 9) (column 3 lines 7-11, column 3 line 16 – column 4 line 46, column 4 lines 50-51, column 7 line 17 – column 8 line 44, and column 11 line 28 – column 12 line 52), wherein the welded portion is created by spot or butt-resistance welding (column 3 lines 7-11, column 3 line 16 – column 4 line 46, column 4 lines 50-51, column 7 line 17 – column 8 line 44, and column 11 line 28 – column 12 line 52); and
- (c) wherein the welded portion between the first and second wires is located proximal the proximal end of a spiral coil (280) (as best seen in Figure 9) (column 3 lines 7-11, column 3 line 16 – column 4 line 46, column 4 lines 50-51, column 7 line 17 – column 8 line 44, and column 11 line 28 – column 12 line 52).

13. Thus for claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35, the claimed invention would have been obvious because the substitution of one known wire joining configuration for another known wire joining configuration would have yielded the predictable results of welding two guidewire components together to one of ordinary skill in the art at the time of the invention. Because both Palermo and Reynolds teach joining methods for components of guidewires, it would have been obvious to one skilled in the art at the time of the invention to substitute one joining method for the other to achieve the predictable results of securely welding two adjacent wire components of a composite guidewire to configure a guidewire to traverse tortuous vasculature.



***Response to Arguments***

14. Applicant's arguments with respect to claims 1-3, 12-21, 23, 24, 27, 28, 30, and 32-35 have been considered but are moot in view of the new ground(s) of rejection, wherein the new ground(s) of rejection relies upon additional claimed limitations defining a new scope of invention and relies upon a new and/or different interpretation and/or different embodiments disclosed in and/or taught by the prior art.

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736